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### REMARKS

#### STATUS OF CLAIMS

Claims 1-42 are pending in the application, claim 1 being the only independent claim. Claims 2-4, 6-8, 12-15, 20, 21, 24, 25, 27-30, and 33-38 have been withdrawn in response to a Restriction Requirement by the Examiner.

#### Response to Restriction

Applicant previously responded to certain of the Examiner's requests for species election with traverse.

For example, applicant had traversed the requirement for restriction between claim 10 (microparticles are microspheres), claim 12 (at least two populations of microparticles that are of different composition from one another) and claim 13 (at least two populations of microparticles having different size distributions), citing as authority MPEP 806.04(f), which requires that claims to differing species be mutually exclusive. MPEP 806.04(f) explicitly states that *"to require restriction between claims limited to species, the claims must not overlap in scope"* (emphasis added, extraneous punctuation removed). Claims 10, 12 and 13 are clearly *not* mutually exclusive, so the requirement is improper.

The Examiner has responded by urging that "the species are not obvious variants of one another" but this is only relevant where applicant traverses on the ground that the species are not patentably distinct. Applicant has not traversed on this ground, but rather has traversed based on the provisions of MPEP 806.04(f).

The Examiner has also pointed to "mutually exclusive characteristics" of the species, apparently in reference to the heading for MPEP 806.04(f) in a previous version (see, e.g., August 2001 version). As noted above, MPEP 806.04(f) fully supports the applicant's traversal, explicitly stating that, "to require restriction between claims limited to species, the claims must not overlap in scope". This is a clear and unambiguous statement of law.

Consideration of claims 12 and 13 is requested.

Applicant had also traversed the requirement for restriction between the following allegedly patentably distinct species of medical article:

- a. comprising adhesive and therapeutic agent (claims 1-23, 26, 29-33 and 35-42);

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- b. comprising additional biodisintegrable adhesive and additional therapeutic agent (claims 24-25);
- c. comprising first and second adhesive regions (claim 27);
- d. comprising first and second different therapeutic agent (claim 28); or
- e. comprising the structure of claim 34.

Specifically, the requirement was traversed because forgoing species are not mutually exclusive (e.g., category a is not mutually exclusive with categories b, c, d and e; category b is not mutually exclusive categories c, d and e; etc.).

Consideration of claims 24, 25, 27-30 and 34-38 is therefore requested.

**Rejection under 35 U.S.C. 102(e)**

Claims 1, 5, 9, 10, 16-19, 22, 23, 26, 40, and 41, are rejected under 35 U.S.C. 102(e) as being anticipated by Zhong et al US 2003/0100830 (Zhong). This rejection and its supporting remarks are respectfully traversed for at least the following reasons.

For a reference to anticipate a claim it must disclose each an every element of the claim. See MPEP 2131 and cases cited therein, especially *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (CCPA 1978).

Claim 1, the only dependent claim presently pending, is directed to a medical article comprising: (a) an adhesive region comprising an adhesive and (b) a therapeutic agent, *wherein said therapeutic agent is adhered to a surface of said adhesive region*, with the proviso that said therapeutic agent is adhered to said surface of said adhesive region in a form other than within spray dried microparticles that comprise said therapeutic agent and a carrier polymer.

Zhong discloses implantable or insertable medical devices comprising (a) a substrate and (b) a hydrogel polymer coating at a least a portion of the surface of the substrate, wherein the hydrogel polymer is adapted to render the medical device visible under magnetic resonance imaging (MRI) upon insertion or implantation of the medical device into a patient. Abstract.

Citing paragraph [0069], the Examiner urges that the device comprises therapeutic agent on the surface of the polymeric material as a result of soaking or dipping the coated device in a solution of therapeutic agent, followed by drying. However, paragraph [0069] describes techniques whereby therapeutic agent is *incorporated into* a hydrogel coating, rather than describing techniques whereby therapeutic agent is *adhered to* a surface of an *adhesive region* as

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claimed. (As the term is used in the present specification, "adhesives" are "materials that are capable of binding therapeutic agents and microparticles upon contact with the same.")

Reconsideration and withdrawal of the rejection under 35 U.S.C. 102(e) is therefore respectfully requested.

#### **Rejections under 35 U.S.C. 103(a)**

Various claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong alone or Zhong in combination with one or more additional references.

Specifically, claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Lang et al. (US 6,592,895 "Lang"). Claims 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Pinchuk et al. (US 6,545,097 "Pinchuk"). These rejections and their supporting remarks are respectfully traversed.

Moreover, it is noted that Zhong did not issue until May 29, 2003--a date subsequent to the filing date of the present application. Thus, this patent falls within the confines of 35 U.S.C. § 102(e)(2): "A person shall be entitled to a patent unless...(e) the invention was described in...(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent..."

It is further noted that the assignee of Zhong (Boston Scientific Scimed, Inc.) and the assignee of the present application are one and the same. 35 U.S.C. § 103(c) reads as follows: "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

#### **Statement concerning common ownership**

In this regard, and in compliance with M.P.E.P. 706.02(I)(2), it is submitted that the present Application No. 10/816,677 and Pub. No. US 2003/0100830 were, at the time the claimed invention of Application No. 10/816,677 was made, both owned by the same person or subject to an obligation of assignment to the same person.

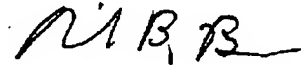
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Consequently, the subject matter of Zhong does not preclude patentability under 35 USC 103(a). Reconsideration and withdrawal of the various rejections under 35 U.S.C. 103(a) are therefore respectfully requested.

### CONCLUSION

In view of the above, Applicant submits that all pending claims are in condition for allowance. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed. All fees due and owing in respect to this Amendment may be charged to deposit account number 50-1047.

Respectfully submitted,




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I hereby certify that this correspondence is being deposited with the United States Patent and Trademark Office on 6/17/2008 via facsimile to: 571-273-8300

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